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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,397	09/29/2006	Irene Corthesy-Theulaz	3712036.00723	8632

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,397	CORTHESY-THEULAZ ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of remarks and amendments to the claims dated 1/21/2010 is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 11/20/2006 remains noncompliant with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

In view of the new amendments to the claims, the rejections and objections that are not reiterated in the current Office Action are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Farmer et al**. US 7374753 (Farmer) in view of the combination of (Pei et al., US publication 20050244392 (Pei) and **Kan Shida et al**. "Enterotoxin-binding glycoproteins in a Proteose-Peptone Fraction of Heated Bovine Milk", J Dairy Science 77:930-939, 1994 (hereinafter Shida)) and in view of **Ivey et al.** US 20040052895 (hereinafter Ivey) and further in view of **Dubos et al.** "Preparation and Properties of Shiga Toxin and Toxoid" From the laboratories of the Rockefeller Institute for medical research, New York and the biological laboratories of E. R. Squibb and sons, New Brunswick, published April 27, 1945 (hereinafter Dubos).

Farmer teaches a composition for oral administration to the intestinal tract for inhibiting bacterial gastrointestinal infections. Methods and systems using the compositions for treating gastrointestinal infections (abstract). The compositions of the invention suitable for use in preventing, treating or controlling gastrointestinal bacterial infections, particularly infant bacterial infections, by organisms capable of producing enterotoxin and infections. The recitation that the effects of infection includes failure of gut epithelial integrity diarrhea and other COX-2 mediated effects in claim 2 is an inherent effect of such infections and is inherently included in such patients. Farmer's compositions inhibit growth of Staphylococcus species, Escherichia coli, Gardnerella vaginalis, Aeromonas hydrophilia, and Clostridium species among others. In a preferred embodiment, the method inhibits Staphylococcus aureus, Clostridium perfringens, among others. (col. 4, lines 62+). Peptones and meat extract are used in a culture for B.

coagulans Hammer bacteria which is used in the inhibition of the pathogenic bacteria shown supra (example 1). Note that the use of the both peptones and meat extract in example 1 read on instant claim 1 because the claim recites that the two ingredients are used **in the manufacture** of an oral composition which is the case in Farmer's disclosure. The reference teaches that a suitable media for growing B. coagulans include Nutristart 701, PDB (potato dextrose broth), TSB (tryptic soy broth) and NB (nutrient broth), all well known and available from a variety of sources. Media supplements containing enzymatic digests of poultry and fish tissue, and containing food yeast are particularly preferred (col. 8, lines 32+). The composition can be in the form of a pharmaceutically acceptable carrier suitable for oral administration to a human infant, preferably, a powdered food supplement, a infant formula or an oral electrolyte maintenance formulation (col. 4, lines 27+).

Farmer did not disclose the use of whey protein peptones.

Pei teaches probiotic compositions used for prophylaxis or treatment against digestive diseases including diarrhea (p. 1, paragraph [0006]; p. 6, paragraph [0085]). Moreover, Pei et al., teaches that the probiotic composition can be prepared as an infant formula comprising denatured whey proteins (p. 18, paragraph [0167]; p. 19, paragraph [0170], milk fat, proteins and fermented based fermented products (page 5, paragraph [0074]; page 19, paragraph [0168]). Note that proteins of animal origin are interpreted as meat extracts.

Shida teaches the binding of E coli enterotoxin to caseins, whey, proteins, etc. The reference discloses that milk contains various protective factors against bacterial pathogens and their toxins. Ganglioside GMI in milk inhibits the activity of *Escherichia* **coli** heat-labile enterotoxin **(LT)** and cholera toxin **(CT)**, which cause diarrhea in humans and animals. The LT and CT are structurally and functionally very similar. Each toxin is made up of five B subunits, which bind to GM1 receptor on the surface of the intestinal epithelia, and a single **A** subunit,

which crosses cell membrane, activates adenylate cyclase, and causes diarrhea. GM1 in milk is thought to prevent the binding of the toxins by competition with the cell surface GMI receptor (see introduction). It is noted that peptide size required for instant claim 5 is elected to compete with the five B subunits which bind to GM1 receptor.

Thus, it would have been obvious to a person having ordinary skill in the art at the time the claimed invention was made to combine whey protein as taught by Pei to enhance the effect of a composition made to treat gastrointestinal infections and because Shida teaches inhibiting or treating enterotoxin-producing bacteria such as E coli and vibrio cholera by using whey and proteins.

Farmer discloses that the media containing food yeast are particularly preferred (col. 8, lines 32+). However neither of the Farmer or Shida disclosed the amount.

Ivey teaches a composition for inoculating poultry and other animals with living cells such as yeast or bacteria. The animal is fed the composition to produce the desired effect [0009]. The yeast is used in an amount of about 0.15% [0088- example 15].

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to follow Ivey's disclosure of the amount of yeast because Farmer teaches that comprising yeast is preferred in a composition used for inhibiting enterotoxin-producing bacteria.

None of the references teaches the amounts of peptones and meat extract required by instant claims.

Dubos teaches a preparation and properties of *shiga* toxin and Toxoid. To prepare the concentrate the reference comprised 500 gm. peptone 1 125 gm. meat extract 1 2500 ml. H20 then used 50 ml concentrate in the preparing the broth which makes an amount of 5 vol.% of

the broth. Therefore, the amounts of peptones and meat extract are between 0.3 to about 7% by volume which reads on the amounts disclosed in the instant claim 1.

It would have been obvious to a person having ordinary skill in the art at the time the claimed invention was made to start at the amounts disclosed by Dubos and optimize the amounts to obtain the intended composition that inhibit or treat the enterotoxin-producing pathogens as disclosed by Farmer, Pei, Shida, and Ivey. The skilled artisan would expect success in making an oral composition comprising peptones (of whey), meat extract, and yeast to inhibit enterotoxin-producing pathogens.

It is noted that the references do not teach compositions comprising all of the claimed elements together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above (Farmer, Pei, Shida, and Ivey), since each element is well known in the art for its same purpose of treatment or prophylaxis against enterotoxin effects. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

Double Patenting

Claims 1-3 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 10/595396. Applicant has stated to reassess this rejection at a later time.

Response to Arguments

Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendments to the claims and correcting dependency resulted in new grounds of rejection to reject claims 1-11. Applicant's arguments are based on cancelling claim 4 and adding its limitations to claim 1. However, the arguments render moot in view of relying upon Pei, Shida, Ivey, and Dubos.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NABILA G EBRAHIM/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618